UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,348	01/30/2004	Ramachandran Thembalath	124907-00107	6363

27557 7590 11/01/2007

BLANK ROME LLP
600 NEW HAMPSHIRE AVENUE, N.W.
WASHINGTON, DC 20037

EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,348	THEMBALATH ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-35,37-47 and 49-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-35,37-47 and 49-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant argues that the restriction to claims 41, 42 and 50 is improper because the original claims are not limited to capsules. None of the independent claims, which have already been examined by the Examiner, are limited to capsules.

However, applicant's attention is called to originally filed claim 29, which is drawn to a capsule. Nonetheless, in view of applicant's argument, the restriction is withdrawn. Claims 41, 42 and 50 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 02/27/07 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 103

Claims 28, 33 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. US 6,248,363.

Patel teaches an oral dosage form comprising paroxetine and salts thereof (column 6, lines 60; and claim 12). The dosage form is coated with ethyl cellulose for a variety of reasons including particle porosity reduction, reduce dust, chemical protection, mask taste, reduce odor, and the like (column 42, lines 22-28). The coating further comprises surfactant (column 2, lines 58-67). Patel further teaches a rapid disintegrate coating comprising cellulosic polymer (column 45, lines 28-40).

Patel does not teach the ratio between the surfactant and ethyl cellulose. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine suitable amounts of surfactant and ethyl cellulose to obtain the claimed invention. This is because Patel teaches coating composition comprising ethyl cellulose and surfactant for a wide number of usage including particle porosity reduction, reduce dust, chemical protection, mask taste, reduce odor, and the like (ID), and because Patel teaches the amount of surfactant can be adjusted so as to at least partially solubilize the pharmaceutical active ingredient (column 51, lines 48-53).

Claims 28-35, 37-47 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al., in view of Buxton et al. US 5,601,845 and Chen et al. US 6,270,805.

Patel is relied upon for the reason stated above. Patel does not teach the claimed surfactant.

Buxton teaches a coating composition comprising ethyl cellulose, polysorbate 80 as a surfactant, plasticizer, and mixture of solvent selected from dichloromethane, ethanol, methanol, acetone, and isopropyl alcohol (see abstract, column 2, lines 31-67, and column 3, lines 3-9). Buxton also teaches the process comprising mixing the ingredients of the coating composition, applying the coating to a drug spheroid core, the coated spheroid is filled into gelatin capsule or compressed into tablet (column 3, lines 29-32; and column 4, lines 1-25).

Thus, it would have been obvious to one of ordinary skill in the art to modify the composition of Patel to include polysorbate 80 as a surfactant, because Buxton teaches the use of polysorbate 80 in the coating is known in pharmaceutical art, and because Patel teaching a coating composition comprising a wide variety of surfactant .

In the case that applicant argues that Patel teaches paroxetine hydrochloride in a long list.

Chen teaches a controlled release formulation for water-soluble drugs include diltiazem, and paroxetine hydrochloride (column 3, lines 3-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the spheroid formulation of Patel using paroxetine in view of the teaching of Chen, because Chen teaches

paroxetine is a well known water-soluble drug, and because Chen teaches the similarity of water-soluble drugs including diltiazem and paroxetine (column 3, lines 3-9).

Response to Arguments

Applicant's arguments filed 07/27/07 have been fully considered but they are not persuasive.

Applicant argues that Patel et al. teaches using the claimed polymer for "a variety of reasons," including "particle porosity reduction, reduce dust, chemical protection, mask taste, reduce odor, and the like (see col. 42, lines 22-28). Patel et al. identify the use of ethyl cellulose (see col. 42, lines 28-32) as follows:

.... water soluble cellulose ethers are preferred for this application. HPMC and ethyl cellulose in combination, or Eudragit E100 are particularly suitable for taste masking applications ....

There is no teaching by Patel et al. of an immediate release formulation or a coating having a ratio of surfactant ethyl cellulose of 1.00:0.165.

However, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, *including nonpreferred embodiments*. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998). Patel suggests a coating that comprises ethyl cellulose for a variety of uses. Patel further suggests adding surfactant in the coating (ID). Moreover, Patel suggest

immediate release coating comprising water soluble cellulose ether (column 45, lines 28-39). The transitional phrase "comprising of" in the preamble of the claims does not preclude the additional polymer such as Eudragit® in the coating.

Applicant argues that the cited references, take alone or in combination, fail to disclose every element of the claimed invention. In particular, none of the cited references disclose immediate release formulation having a ratio of surfactant to ethyl cellulose of 1.00:0.165, which is recited in the present independent claims. Additionally, there is no rationale in the cited references or in the art in general to modify the teachings of Buxton et al. and Chen et al. to make an immediate release formulation. Neither Buxton et al. nor Chen et al. teach immediate release (i.e., non-controlled release) drug product formulations using an ethyl cellulose and surfactant coating where the ratio of surfactant to ethyl cellulose is 0.165:1.00, nor do they suggest or imply such a drug product.

However, in response to applicant's argument that "*no rationale in the cited references or in the art in general to modify the teachings of Buxton et al. and Chen et al. to make an immediate release formulation, because neither Buxton et al. nor Chen et al. teach immediate release (i.e., non-controlled release) drug product formulations using an ethyl cellulose and surfactant coating where the ratio of surfactant to ethyl cellulose is 0.165:1.00, nor do they suggest or imply such a drug product*", the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the

test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Buxton is relied upon solely for the teaching of the specific surfactant such as polysorbate 80. Chen is relied upon for the teaching of the specific drug, *e.g.*, paroxetine.

The Declaration under 37 CFR 1.132 filed 08/10/07 is insufficient to overcome the rejection of the present claims based upon the 103(a) rejections over Patel et al., Buxton, and Chen. The Declaration discloses a very specific composition including specific drug in specific amount, and a specific surfactant. The present independent claims do not require paroxetine HCl as well as polysorbate 80.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER

AU1615